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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,032	07/29/2005	Helen Francis-Lang	EX03-068C-US	1012

63572 7590 01/17/2007

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EXAMINER	
WILSON, MICHAEL C	
ART UNIT	PAPER NUMBER
1632	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	01/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/528,032	FRANCIS-LANG ET AL.	
	Examiner	Art Unit	
	Michael C. Wilson	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-25 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-25 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10, drawn to a method of screening for p21 modifying agents using ROR protein or nucleic acid, classified in various classes and subclasses.

II. Claims 11 and 12, drawn to a method of further screening for p21 modifying agents using an animal comprising cells defective in p21 function, classified in class 800, subclass 3.

III. Claims 13-15 and 20-22, drawn to a method of modifying p21 by administering an agent that binds to ROR, classified in various classes and subclasses, for example class 514, subclass 44.

IV. Claims 16-19, drawn to a method of screening for p21 modifying agents using an animal comprising cells expressing ROR, classified in class 800, subclass 3.

V. Claims 23-25, drawn to a method of diagnosing disease using ROR expression, classified in various classes and subclasses.

The inventions are distinct, each from the other because of the following reasons:

Groups I and II are patentably distinct because contacting agents with ROR protein or nucleic acid can be used to identify candidate p21 modulating agents while administering an agent to cells lacking p21 function can be used to identify agents

capable of treating disease linked to a p21 disruption. The steps of each method are different and require different searches and are recognized as divergent assays each requiring their own protocols and reagents. The burden required to search both sets of method steps would be undue. The method of administering agents to cells lacking p21 function can be used independently of the method of contacting an agent with ROR protein or nucleic acid. The method of Group I does not require the method of Group II and the method of Group II does not require the method of Group I.

Groups I and III are patentably distinct because contacting an agent with an ROR protein or nucleic acid is used to identify candidate p21 modulating agents while administering p21 modulating agents is used to treat disease. The protocols and reagents required to identify p21 modulating agents are materially distinct and separate than those required to treat disease using a p21 modulating agent. The method of identifying p21 modulating agents does not require modulating p21 and the method of modulating p21 does not require identifying p21 modulating agents. The burden required to search both methods together would be undue.

Groups I and IV are patentably distinct because contacting agents with ROR protein or nucleic acid can be used to identify candidate p21 modulating agents while administering an agent to cells expressing ROR can be used to identify agents capable of treating disease linked to ROR overexpression. The steps of each method are different and require different searches and are recognized as divergent assays each requiring their own protocols and reagents. The burden required to search both sets of method steps would be undue. The method of administering agents to cells expressing

ROR can be used independently of the method of contacting an agent with ROR protein or nucleic acid. The method of Group I does not require the method of Group IV and the method of Group IV does not require the method of Group I, i.e. the methods do not have to be used together.

Groups I and V are patentably distinct because contacting an agent with an ROR protein or nucleic acid is used to identify candidate p21 modulating agents while determining ROR expression in a sample is used to determine the likelihood of disease. The protocols and reagents required to identify p21 modulating agents are materially distinct and separate than those required to determine how ROR expression in a sample is linked to disease. The method of identifying p21 modulating agents does not require diagnosing disease and the determining the likelihood of disease does not require identifying p21 modulating agents. The burden required to search both methods together would be undue.

Groups II and III are patentably distinct because administering an agent to cells lacking functional p21 is used to identify candidate p21 modulating agents while administering p21 modulating agents is used to treat disease. The protocols and reagents required to identify p21 modulating agents are materially distinct and separate than those required to treat disease using a p21 modulating agent. The method of identifying p21 modulating agents does not require modulating p21 and the method of modulating p21 does not require identifying p21 modulating agents. The burden required to search both methods together would be undue.

Groups II and IV are patentably distinct because administering agents to cells lacking functional p21 in vitro or in vivo can be used to identify candidate p21 modulating agents capable of treating disease linked to p21 disruptions while administering an agent to cells expressing ROR can be used to identify agents capable of treating disease linked to ROR expression. The steps of each method are different cells (i.e. cells lacking functional p21 vs. cells overexpressing ROR) and require different searches. The burden required to search both sets of method steps would be undue. The method of administering agents to cells lacking functional p21 can be used independently of the method of administering agents to cells expressing ROR. The method of Group II does not require the method of Group IV and the method of Group IV does not require the method of Group II, i.e. the methods do not have to be used together.

Groups II and V are patentably distinct because contacting an agent with cells lacking p21 expression is used to identify candidate p21 modulating agents while determining ROR expression in a sample is used to determine the likelihood of disease. The protocols and reagents required to identify p21 modulating agents are materially distinct and separate than those required to determine how ROR expression in a sample is linked to disease. The method of identifying p21 modulating agents does not require diagnosing disease and the determining the likelihood of disease does not require identifying p21 modulating agents. The burden required to search both methods together would be undue.

Groups III and IV are patentably distinct because modulating p21 can be used to treat disease while administering an agent to cells expressing ROR can be used to identify agents capable of treating disease linked to ROR expression. The steps of each method require different searches. The burden required to search both sets of method steps together would be undue. The method of administering agents to modulate p21 can be used independently of the method of identifying p21 modulators by administering agents to cells expressing ROR. The method of Group III does not require the method of Group IV and the method of Group IV does not require the method of Group III, i.e. the methods do not have to be used together.

Groups III and V are patentably distinct because modulating p21 can be used to treat disease while determining ROR expression in a sample is used to determine the likelihood of disease. The protocols and reagents required to modulate p21 are materially distinct and separate than those required to determine how ROR expression in a sample is linked to disease. The method of modulating p21 does not require diagnosing disease and the method of diagnosing disease does not require modulating p21. The burden required to search both methods together would be undue.

Groups IV and V are patentably distinct because contacting an agent with cells expressing ROR is used to identify candidate p21 modulating agents while determining ROR expression in a sample is used to determine the likelihood of disease. The protocols and reagents required to identify p21 modulating agents are materially distinct and separate than those required to determine how ROR expression in a sample is linked to disease. The method of identifying p21 modulating agents does not require

diagnosing disease and the determining the likelihood of disease does not require identifying p21 modulating agents. The burden required to search both methods together would be undue.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not

distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached at the office on Monday, Tuesday, Thursday and Friday from 9:30 am to 6:00 pm at 571-272-0738.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It

also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on 571-272-4517.

The official fax number for this Group is (571) 273-8300.

Michael C. Wilson

MICHAEL WILSON
PRIMARY EXAMINER